SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5641–5660

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(l), one article was, or purported to be, or was represented as, a drug composed partly of dihydrostreptomycin, a derivative of streptomycin, and another article was represented as a drug containing bacitracin, and neither of the articles was from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New Drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5641. Vitamin B_{12} injection. (F.D.C. No. 41235. S. No. 75–724 M.)

QUANTITY: 52 vials at Riverside, Calif.

SHIPPED: 11–13–57, from Memphis, Tenn., by Morton Pharmaceuticals.

LABEL IN PART: "10 cc Vial * * * Vitamin B_{12} Crystalline USP 1000 micrograms per cc * * * Intramuscular-Intravenous."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 988 micrograms of cyanocobalamin (vitamin B_{12}), 9.05 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material, the presence of which was not stated on the label.

LIBELED: 12–20–57, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a substantial amount of unidentified

dissolved material in addition to those constituents permitted to be present in *cyanocobalamin injection;* 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: 3–23–59. Consent—destruction.

5642. Vitamin B_{12} injection. (F.D.C. No. 40316. S. No. 43–464 M.)

QUANTITY: 3 ctns. containing a total of 1,550 10-cc. vials at St. Louis, Mo.

SHIPPED: 5–20–57, from Chicago, Ill., by Hallmark Laboratories, Inc.

LABEL IN PART: (Shipping ctns.) "Vitamin B_{12} 1000 mcg. per cc (Cyanocobalamin, U.S.P.) in water for injection. Sodium chloride 0.9% Benzyl alcohol as bacteriostatic agent, 2% average dose: 1 cc for intramuscular and intravenous use. * * * Hallmark Laboratories, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 978 micrograms of cyanocobalamin (vitamin B_{12}), 8.32 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

LIBELED: 6–7–57, E. Dist. Mo.; amended libel 6–18–57 and 4–4–58.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a quantity of dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection;* and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: Hallmark Laboratories, claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories which claimant answered in part and objected to in part. Subsequently, the Government filed a motion to compel further and more complete answers and also a motion for discovery and production of documents. The claimant took issue with the Government's motions, and after a hearing on 12–16–58, the court ordered the claimant to answer some of the interrogatories and sustained claimant's objections to the remainder. The Government's motion for discovery and production of documents was sustained. Thereafter, on 3–11–59, claimant having consented, a decree of condemnation was entered and the article was destroyed.

5643. Pyrdex. (F.D.C. No. 40882. S. No. 53–628 M.)

QUANTITY: 340 vials at Bellaire, Tex.

SHIPPED: 8–9–57, from Los Angeles, Calif., by E. S. Miller Laboratories, Inc.

LABEL IN PART: "No. 320 Pyrdex 10 CC. Vial Each CC. Contains Pyrilamine Maleate 25 Mg. Dextro-Amphetamine HCL 2 Mg. * * * Control #16071."

LIBELED: On or about 10–28–57, S. Dist. Tex.

CHARGE: 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 7–31–58. Consent—destruction.